IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/798,786
Appellant:	Robert A. Van Tassel et al.
Filed:	March 10, 2004
Title:	METHODS FOR TREATMENT OF ANEURYSMS
T.C./A.U.:	3739
Examiner:	Roy Dean Gibson
Confirmation No.:	5624
Docket No.:	BSI-557US1 (formerly ENDOV-67986)

APPEAL BRIEF IN SUPPORT OF NOTICE OF APPEAL REINSTATING APPEAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby request reconsideration and reversal of the Rejection dated May 29, 2008 of claims 61-66, 68-71 and 73. A second Notice of Appeal was filed on August 29, 2008 to reinstate this Appeal after the Examiner re-opened prosecution.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the second Notice of Appeal, whichever is later.

The difference in current fees ($540) for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) relative to the fees previously paid ($500), namely $40, is provided herewith.

I. REAL PARTY IN INTEREST

The real party in interest is Endovascular Technologies, Inc., the assignee of record, which is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 61-71 and 73 are pending. Claim 67 is allowed. Claims 61-66, 68-71 and 73 stand rejected. Claims 61-66, 68-71 and 73 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the May 29, 2008 rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in the pending independent method claim 61, the presently claimed invention relates to a method for increasing the adventitial mass of a tissue by administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial layer, and applying energy to the target tissue of the blood vessel wall so that the photoactivatable agent is activated to increase the adventitial volume.

As explained in the specification, beginning on page 8, line 24, the phrase "theraputically effective amount" as used in the application refers to "an amount effective, at dosages and for periods of time necessary, to achieve a desired result." Continuing at page 9, line 6, the phrase "photoactivatable agent" as used in the application refers to "a material which becomes activated by light energy." The specification explains on page 1, lines 11-15, that the adventitial layer of tissue is the outer layer of the tissue. Furthermore, as explained beginning on page 7, line 26, the term "energy" as used in the application refers to "any source from the electromagnetic spectrum that is applied for a duration, and an intensity to cause the desired result." Figure 1 illustrates the effect of psoralen-ultra violet A therapy on the adventitial area of a blood vessel.

As set forth in the pending independent method claim 69, the presently claimed invention relates to a method for treating tissue of a subject by applying an agent and irradiating a target region of tissue with UVC irradiation and inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue; wherein the step of irradiating the target region further comprises irradiating the target region externally using an external light delivery source."

As explained in the specification, beginning on page 12, line 2, the present invention can be practiced in conjunction with the administration of photoactivatable agents. As explained beginning at page 9, line 6, the phrase "photoactivatable agent" as used in the application refers to "a material which becomes activated by light energy." The specification explains on page 1, lines 11-15, that the adventitial layer of tissue is the outer layer of the tissue. The

specification further explains on page 8, beginning at line 4, that, in summary, "[f]ibrosis is a response to injury in which new extracellular matrix is laid down producing dense amounts of collagen required for wound healing." The specification explains on page 16, lines 17-20, that the photoactivatable agent may be activated externally. "For example, using a monochromatic light source applied to an area of the subject's body requiring treatment, for example, the chest area. Such external light sources are well known in the art, for example, a monochromatic light source, e.g. a UV lamp." Figure 1 illustrates the effect of psoralen-ultra violet A therapy on the adventitial area of a blood vessel.

As set forth in the pending independent method claim 70, the presently claimed invention relates to a method for treating tissue of a subject by applying an agent and irradiating a target region of tissue with UVC irradiation and inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue; wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter."

As explained in the specification, beginning on page 12, line 2, the present invention can be practiced in conjunction with the administration of photoactivatable agents. As explained beginning at page 9, line 6, the phrase "photoactivatable agent" as used in the application refers to "a material which becomes activated by light energy." The specification explains on page 1, lines 11-15, that the adventitial layer of tissue is the outer layer of the tissue. The specification further explains on page 8, beginning at line 4, that, in summary, "[f]ibrosis is a response to injury in which new extracellular matrix is laid down producing dense amounts of collagen required for wound healing." The specification explains on page 16, lines 12-16, that the photoactivatable agent may be activated internally. "The non-occluding catheter can be used to deliver light or UVA energy to the target region in the vessel wall while permitting blood flow through the vessel wall." Figure 1 illustrates the effect of psoralen-ultra violet A therapy on the adventitial area of a blood vessel.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 61, 62, 64-66 and 68 are unpatentable under 35 U.S.C. § 102(a) as anticipated by U.S. Patent No. 6,488,673 (Laufer et al.).

B. Whether claims 63, 69-71 and 73 are unpatentable over U.S. Patent No. 6,488,673 (Laufer et al.) in view of U.S. Patent No. 5,913,884 (Trauner et al.) under 35 U.S.C. § 103(a).

VII. ARGUMENT

A. Rejection Under 35 U.S.C. §102(e) Over U.S. Patent No. 6,488,673

Claims 61, 62, 64-66 and 68 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,488,673 (Laufer et al.). It is respectfully submitted, however, that the pending claims are patentable over Laufer et al. for at least the reasons set forth below.

Anticipation requires that each and every limitation of the claim be disclosed, either expressly or under principles of inherency, in a single prior art reference. *In re* Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Absence from the reference of any claimed limitation negates anticipation. *Rowe v. Dror*, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Independent claim 61 recites:

"A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue."

The May 29, 2008 Office Action indicates on page 3 that "Laufer et al. disclose a method of applying heat to the inner wall of a vessel... after applying a photo-activatable agent (a psoralen agent injected intravenously) to the vessel and which is necessarily taken up by the wall and the adventitial area of the vessel..." (emphasis added).

The Office Action acknowledges that Laufer et al. teaches applying heat to the inner wall. The Office Action does not include a basis in fact and/or technical

reasoning to reasonably support that the heating of the inner wall inherently heats the outermost connective tissue of the vessel (adventitial area of the tissue).

As set forth in M.P.E.P. §2112, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In Ex parte Levy, the Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

Contrary to the position set forth, as explained at column 26, lines 35-37, Laufer et al. specifically teaches using the light delivery source "to irradiate the smooth muscle surrounding the airways to induce fibrosis and/or destroy smooth muscle tone of the airway." As explained at column 7, lines 30-36, and shown in Fig. 5, reproduced below, the smooth muscle 27 is an inner layer surrounded by stoma 32, mucous glands 34 and cartilage 36."

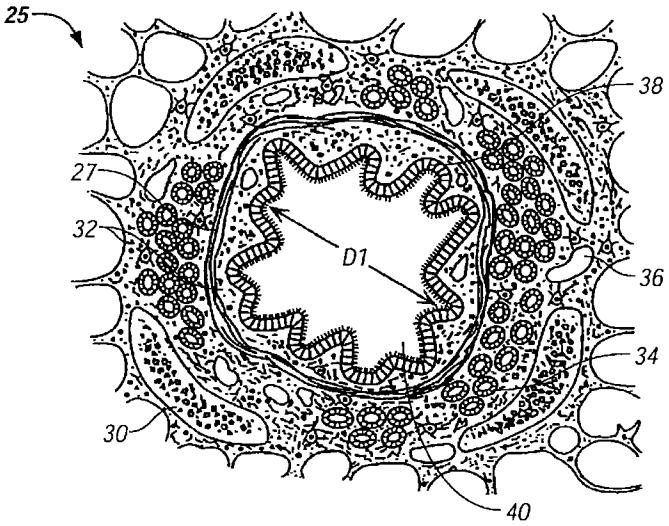

FIG. 5

Laufer et al. does not teach or suggest applying an agent such that it is taken up by the adventitial area of a target tissue or increasing an adventitial area in the area of the target tissue.

Furthermore, Trauner et al., which is also of record, Trauner et al. explains at column 2, lines 27-29, that "the modulation can include inhibiting fibrosis by administering a high dose of photodynamic therapy." (emphasis added). As explained at column 2, line 60 to column 3, line 3,

> [a]s used herein, 'low dose' photodynamic therapy means a dose sufficient to kill from 0% to about 10% of all cells exposed to the photoactiviting light if the photosensitizer is untargeted, or from 0% to about 10% of the targeted cells exposed to the photoactiviting light, if the photosensitizer is targeted. As used herein, 'high dose' photodynamic therapy means a dose sufficient to kill from about 10% to about 90% of all cells exposed to the photoactivating light if the photosensitizer is untargeted, or from about 10% to about 90% of the targeted cells exposed to the photoactivating light, if the photosensitizer is targeted.

Trauner et al. teaches that a low dose therapy targets only a small percentage of cells, i.e. 10% or less of the cells, and therefore, it is not inherent that the agent would be taken up in the adventitial area nor that such would inherently result in increasing the adventitial area. If a high dose therapy were utilized, such would result in an inhibiting of fibrosis.

Taking the complete teachings of the cited prior art references, the suggested heating to an extent necessary to heat from the inside surface to the outer surface, would likely result in inhibition of fibrosis, not "increasing an adventitial area in the area of the target tissue" as recited in claim 61.

Since Laufer et al. does not disclose every limitation of the claimed invention, either expressly or inherently, the claimed invention is not anticipated thereby. Appellants respectfully request reconsideration and reversal of the rejection of claims 61, 62, 64-66 and 68 under 35 U.S.C. §102(e).

Accordingly, for at least the above reasons, appellants respectfully contend that independent claims 61, 67 and 69 and dependent claims 62-66, 68, 70, 71 and 73 of this application are now in condition for allowance. Accordingly, appellants respectfully request reversal of the Final Rejection.

B. Rejection Under 35 U.S.C. §103(a) Over U.S. Patent No. 6,488,673 in View of U.S. Patent No. 5,913,884

Claims 63, 69-71 and 73 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,488,673 (Laufer et al.) in view of U.S. Patent No. 5,913,884 (Trauner et al.). It is respectfully submitted, however, that the pending claims are patentable over Laufer et al. and Trauner et al. in any reasonable combination for at least the reasons set forth below.

Claim 63 is depends from claim 61. As acknowledged in the November 26, 2007 Office Action withdrawing the 35 U.S.C. § 102 rejection based on Trauner et al., Trauner et al. does not overcome the shortcomings of Laufer et al. explained above.

Furthermore, claim 63 further recites that the step of administering a therapeutically effective amount of a photoactivatable agent such that it is taken up by the adventitial area of the target tissue "further comprises locally administering the photoactivatable agent." The May 29, 2008 Office Action acknowledges that "Laufer et al. fail to disclose local administration of the photo-activatable agent." The Office Action cites to Trauner et al. as teaching such feature, however, Trauner et al. teaches that the photosensitizer is delivered to a wound site, not to an adventitial area of the target tissue. Furthermore, Trauner et al. explains at column 3, line 66 through column 4, line 13, that the photosensitizer is targeted to macrophages and myofibroblasts, i.e. to a specific target. No where in Trauner et al. is it disclosed that such specific target would be the adventitial area of a target tissue.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention. Appellants respectfully request reconsideration and reversal of the rejection of claim 63 under 35 U.S.C. §103(a).

Independent claim 69 recites:

"A method for treating tissue of a subject comprising,

applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and

inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue;

wherein the step of irradiating the target region further comprises irradiating the target region externally using an external light delivery source."

The May 29, 2008 Office Action acknowledges that "Laufer et al. fail to disclose irradiating the target region externally using an external light source." The Office Action cites to Trauner et al. as teaching such feature, however, Trauner et al. teaches at column 7, lines 39-42 that "delivery of the light used to photoactivate the photosensitizer is limited to the wound site and the area immediately surrounding the wound site. This minimizes undesirable cytotoxic side effects." Since neither Laufer et al. or Trauner et al. teach application of the agent to the adventitial layer, the proposed combination of utilizing external light would require delivering light to a further area than the area of the agent, contrary to the teaching of Trauner et al.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention, but instead teach away from the claimed invention. Appellants respectfully request reconsideration and reversal of the rejection of claim 69 under 35 U.S.C. §103(a). Claim 73 depends from claim 69 and is therefore allowable for at least the reasons set forth above.

Independent claim 70 recites:

"A method for treating tissue of a subject comprising,

applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and

inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue; wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter."

As explained above, neither Laufer et al. or Trauner et al. teach application of the agent to the adventitial layer. Furthermore, as explained above, Trauner et al., explains that a high dose of therapy will inhibit fibrosis. The suggested heating to an extent necessary to heat from the inside surface to the outer surface, would likely result in inhibition of fibrosis, contrary to the claimed inducing fibrosis or increasing the adventitial layer.

It is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention, and instead teach away from the claimed invention. Appellants respectfully request reconsideration and reversal of the rejection of claim 70 under 35 U.S.C. §103(a). Claim 71 depends from claim 70 and is therefore allowable for at least the reasons set forth above.

VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Such actions are respectfully requested.

Respectfully Submitted,

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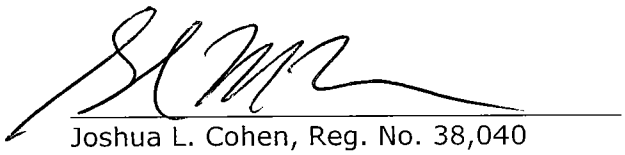

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

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The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

CLAIMS APPENDIX

1-60. (Canceled)

61. A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue.

62. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises systemically administering the photoactivatable agent.

63. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises locally administering the photoactivatable agent.

64. The method of claim 61, wherein the step of administering a therapeutically effective amount of a photoactivatable agent further comprises administering a psoralen agent or derivatives thereof.

65. The method of claim 61, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue internally using a light delivery catheter.

66. The method of claim 65, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue using a light delivery catheter without occluding fluid flow.

67. A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue, wherein the step of applying energy to the target tissue further comprises irradiating the site of an aneurysm externally using an external light delivery source.

68. The method of claim 61, wherein the step of applying energy to the target tissue further comprises irradiating the target tissue with UV irradiation.

69. A method for treating tissue of a subject comprising,

applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and

inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue;

wherein the step of irradiating the target region further comprises irradiating the target region externally using an external light delivery source.

70. A method for treating tissue of a subject comprising,

applying an agent and irradiating a target region of tissue with UVC irradiation to accomplish an interaction between the agent and the UVC irradiation; and

inducing fibrosis or increasing an adventitial layer in at least one layer of the tissue; wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter.

71. The method of claim 70, wherein the step of irradiating the target region further comprises irradiating the target region internally using a light delivery catheter without occluding fluid flow.

72. (Canceled)

73. The method of claim 69, wherein the step of irradiating the target region further comprises irradiating the target region with UVC irradiation having a wavelength of about 240 to 370 nanometers.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None